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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,148	12/02/2004	Alan Michael Sawyer	2004_1542A	9045

513 7590 06/23/2009

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,148	SAWYER ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-13,16,17 and 20-31* is/are pending in the application.

4a) Of the above claim(s) *16,17,20-26,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-13,27,28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Sawyer et al.

1. Applicant's response filed on 5/18/2009 is acknowledged. Claims 1, 2, 4-13, 16, 17 and 20-31 are pending. Claims 3, 14, 15, 18 and 19 have been cancelled. Claims 16, 17, 20-26, 29 and 31 have been withdrawn from consideration. Claims 1, 7 and 27 have been amended.

2. Claims 1, 2, 4-13, 27, 28 and 30 are under examination. Due to species election, claims are examined to the extent that the purified candidate antigens are purified proteinaceous substances, and the purified proteinaceous substances are peptides.

Objections Withdrawn

3. The objection to claim 7 for reciting "wherein the antibody-producing cells are B cells, T cell or stem cells" is withdrawn in view of applicant's amendment to the claim.

Objections Maintained

4. The objection to claim 27 for reciting the phrase "a single suspension of antibody-producing cells" is maintained.

Although applicants have amended the claim to recite "a single cell suspension that produce antibodies against a plurality of antigens", the amended claim recites "said immortalized cell lines are generated from a single cell suspension that produce antibodies against a plurality of antigens". A single cell suspension would not make a plurality of immortalized cell lines that produce a plurality of different antibodies.

Rejection Maintained

Claim Rejections - 35 USC § 103

5. The rejection of claims 1, 2, 4-13, 27, 28 and 30 under 35 U.S.C. 103(a) as being unpatentable over Chen (CN 1274085A, Pub. Date: 11/22/2000, see the English translation submitted with IDS on 5/3/2007), in view of Rava et al (US Patent 6,720,149; Date of Patent: 4/13/2004, earliest effective filing date: 6/7/1994), Klessing et al. (US 5,989,846, Date of Patent: 11/23/1999), Poethke et al. (Biol. Chem., 1997, 378: 997-1004), Hu (US 2002/0048823A1, Pub. Date: 4/25/2002, earliest effective filing date: 8/11/2000), and Sanderson et al. (US, 6,821,517B1, Date of Patent 11/23/2004, earliest effective filing date: 10/18/1996) is maintained.

The response states that the method of Chen differs from the claimed method in that it involves immunization with homogenized tissue, rather than with a plurality of purified candidate antigens, and Chen involves identifying a monoclonal antibody against a particular antigen using a chip displaying antibodies, i.e., by spotting monoclonal antibodies onto a chip, adding the antigen and detecting the binding of the antigen to a monoclonal antibody using polyclonal antibodies produced in a separate step. However, the instant method uses chips displaying antigens for identifying a monoclonal antibody. Rava does not provide motivation to use chips displaying peptides in the method of Chen. The response states that the obviousness rejection was made with hindsight and knowledge of the current invention. The response states that the use of purified candidate antigens and the use of antigen chips would not have been minor substitutions; making these changes would have required the skilled person

to adopt a completely different mindset and make significant modifications to the method employed by Chen. The response states that enormous advantages are obtained by using the method of the invention in comparison with the laborious prior art methods for producing monoclonal antibodies in Chen.

Applicant's arguments have been carefully considered but are not persuasive. Although Chen does not teach screening antibodies using a chip displaying antigens, it was known in the art that the screening is based on the antibody-antigen interaction, and can be carried out by using either a chip displaying antibodies or a chip displaying antigens, as evidenced by Rava and Poethke et al. Rava et al teach the use of a biological chip having a molecular probe array for detecting monoclonal antibodies, wherein the probe is selected from proteins of interest (abstract, detailed description, paragraph 3; in particular). Poethke et al. teach immunizing mice with a mixture of eight synthetic ChAT-peptides coupled to KLH (20 microgram each), and screening of hybridoma supernatants using ELISA, wherein a mixture of 8 peptides was employed for coating the microtiter plate and the immobilized peptides were challenged with the hybridoma supernatants (see page 1003, paragraphs 2 and 3). While Chen does not disclose immunizing animals with purified proteinaceous substance, purified proteins were used in the prior art for producing a plurality of antibodies, as shown by Klessig, Poethke, and Hu. Klessig et al. teach immunizing mice with a purified protein mixture comprising two prevalent proteins and a number of other less abundant proteins (see column 26, lines 40-43). Klessig et al. disclose that the progeny of each independent B cell fused with a myeloma cell were grown separately, and the monoclonal antibody was

individually tested to determine if the antibody recognized any one of the proteins in the partially purified protein mixture (see column 26, lines 54-65). Poethke et al. teach immunizing mice with a mixture of eight synthetic ChAT-peptides coupled to KLH (20 microgram each), and screening of hybridoma supernatants using ELISA, wherein a mixture of 8 peptides was employed for coating the microtiter plate and the immobilized peptides were challenged with the hybridoma supernatants (see page 1003, paragraphs 2 and 3). Hu discloses that a plurality of monoclonal antibodies can be produced by immunizing one or more animals with randomized peptides or natural antigens (see paragraph [0010]). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Chen to immunize the animals with purified proteins (or peptides) for the production of a population of monoclonal antibodies that bind the purified proteins (or peptides) and further use the protein chip coated with the purified proteins (or peptides) for large scale screening of monoclonal antibodies in view of the teachings of Rava, Klessing, Poethke, and Hu. One of ordinary skill in the art would have been motivated to do so because purified proteins (or peptides) were used in the prior art to produce monoclonal antibodies that bind them, as well as identify the produced monoclonal antibodies, as shown by the teachings of Klessing, Poethke and Hu. Applicant s arguments of hindsight reasoning have been carefully considered but are not persuasive to overcome the rejection. "Any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was

made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." Ln re McLaughlin 443. F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). In the instant case, Chen teaches a method of preparing a plurality of monoclonal antibodies comprising immunizing an animal with homogenized tissue and identifying the monoclonal antibodies using a chip displaying antibodies. Rava and Poethke disclose that monoclonal antibodies can be identified using a chip displaying antigens or a plate coated with antigens. Klessig, Poethke, and Hu teach preparation of a plurality of monoclonal antibodies by immunizing an animal with purified antigens, and further isolate and identify the antibodies that bind to the purified antigens. Thus the use of purified proteins to make a plurality of monoclonal antibodies and further isolate and identify the antibodies using an array displaying the purified antigens were clearly in the purview of those of ordinary skill in the art and was within the knowledge of 'those in the art at the time the invention was made.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. For these reasons, the rejection is maintained.

Conclusion

6. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643

/Christopher H Yaen/
Primary Examiner, Art Unit 1643